

REMARKS

The Office Action mailed December 11, 2006 has been received and reviewed. Claims 1-3 and 5-20 are currently pending in the application. All claims stand rejected. Reconsideration is respectfully requested.

35 U.S.C. § 103(a)

Claims 1-20 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Wilson *et al.* (US 2002/0051844 A1) in view of Mahan "Digestibility of soybean meals collected at four periods from a soybean processor (Cargill) in Ohio". Applicant respectfully traverses the rejection.

To establish and maintain a *prima facie* case of obviousness under 35 U.S.C. § 103, M.P.E.P. § 706.02(j) states that, first, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim elements.

The Examiner asserts that Wilson *et al.* teach animal feed compositions and methods for increasing the reproductive performance of breeding populations of swine. The compositions of Wilson *et al.* comprise ω -3-fatty acids. These may be added to a random animal feed, such as soybean meal. As optional ingredients, Wilson *et al.* mention lysine, methionine, arginine, threonine, tryptophan and cysteine.

However, Wilson *et al.* is directed to the effect of ω -3-fatty acids and does not suggest the effect of arginine on the reproductive performance of swine and therefore, lacks any teaching or suggestion to modify the amount of arginine (or lysine to arginine ratio) in its feed. As acknowledged by the Examiner, Wilson *et al.* do not mention specific amounts or relative amounts of amino acids in the animal feed. (December 11, 2006, Office Action, page 3)

In regard to Mahan, Table 2 of Mahan illustrates the composition of soybean meal as including 3.56% arginine, 2.97 % lysine, 0.65% methionine, 0.76% cysteine, 1.83% threonine and 1.70% tryptophan. Relative to the amount of lysine, this gives a total amount of methionine and cysteine of less than 0.55 ($0.65 + 0.76/2.97 = 0.47$). The weight ratio between arginine and

lysine is lower than 1.5 ($(3.56/2.97 = 1.20)$). The Examiner acknowledges that Mahan does not teach or suggest the claimed relative amounts of amino acids. Thus, the combination of Wilson et al. and Mahan fails to teach or suggest every element of the presently claimed invention.

~~It was asserted that because soybean meal naturally contains amino acids, it would be~~ obvious to one of skill in the art to increase the relative amount of such amino acids to achieve the ratios of the presently claimed invention. However, Wilson *et al.* and Mahan, either alone or in combination, do not provide any suggestion or motivation to modify or combine the references. As Wilson is silent regarding any benefit of an increased ratio of methionine/cysteine to lysine and arginine to lysine, one skilled in the art would not be motivated to experiment with the *relative ratios* of these amino acids in the soybean meal of Mahan. Without any motivation, one skilled in the art would not know what changes to make, or what the benefits would be of making such changes, in the formulation of the soybean meal animal feed blend in order to achieve the claimed invention.

It was asserted that Baba et al. teaches that the reproductive activity of L-dopa is significantly enhanced by the combination with one or more amino acids selected from L-arginine, L-ornithine, L-lysine, D-phenylalanine, L-glutamic acid and γ -aminobutyric acid. (December 11, 2006, Office Action, pages 6-7). The amount of L-dopa is usually 0.1 to 2 wt.% of the finished feed and the amount of amino acid is applied within a range from 0.1 to 10 times the amount of L-dopa. (Baba, col. 3, lines 50-57).

The soybean meal of Mahan does not include L-dopa and Wilson is also silent with respect to L-dopa. Accordingly, there is no L-dopa activity to enhance and one skilled in the art would not be motivated by Baba to increase the amount (or relative ratio) of L-arginine in the soybean meal of Mahan. The combined effect of L-dopa and L-arginine is not the same as the effect of L-arginine alone.

Furthermore, even if L-dopa were present in an amount of 0.1 to 2 wt.% in the soybean meal of Mahan, one skilled in the art would not be motivated to add arginine because the soybean meal of Mahan includes arginine in an amount of 3.56wt.% which is within the range suggested by Baba et al. Moreover, Baba et al. does not suggest modifying the ratio of methionine/cysteine to lysine and arginine to lysine as claimed.

The combination of Wilson et al. and Mahan fails to teach or suggest a composition having the claimed ratio of methionine/cysteine to lysine and arginine to lysine or a method which includes providing a diet to at least one gestating animal resulting in a daily dosage of 200 - 1300 mg arginine per kg body weight of at least one gestating animal. Further the references are silent as to any potential benefit of increasing arginine or the methionine/cysteine to lysine and arginine to lysine ratios. As increasing the amount or ratio of these amino acids would significantly increase the cost of the composition, one of skill in the art would not be motivated to make such a composition without being aware of the potential benefit of the investment.

It was asserted that neither Wilson et al. nor Mahan teaches or suggests that any harmful effects of arginine and therefore, one skilled in the art would be motivated to experiment with increased amounts of the amino acid. (December 11, 2006, Office Action, page 6). Baba et al. was relied upon to support this assertion. *Id.* As stated, Baba et al. would not motivate a person skilled in the art to increase the amount of arginine in the Mahan composition that lacks L-dopa. Further, Baba et al (and Wilson et al. and Mahan) fails to teach or suggest increasing the methionine/cysteine to lysine and arginine to lysine *ratio*. Further, as Baba et al. fails to describe its mechanism of reproductive improvement (the Baba et al. formulation is given to both male and female animals), one of skill in the art reading Wilson et al. and Mahan would lack any motivation to make the claimed composition or method.

Indeed, a person of skill in the art would not have been motivated to increase the amount (or relative ratio) of arginine in a feed composition as the National Research Council (NRC), a standard handbook reference for swine breeders, states that swine during pregnancy synthesize all the necessary arginine. (Specification, page 3, lines 9-21). According to this reference, excessive supplements of arginine are undesirable as they can reduce feed intake and reduce growth. As such, one of ordinary skill in the art would not have had a reasonable expectation of success by increasing the arginine content of the feed.

Baba et al., which is directed to compositions including L-dopa and published nearly 30 years ago, cannot discredit the teachings of the NRC. Indeed, the Examples of the present application were unexpected in view of the NRC report. The unexpected results are further highlighted by an Abstract from the American Society of Animal Science (ASAS) Midwest Meeting 2007 titled "Effect of Progenos on Placenta and Fetal Development in Pigs." A copy of

the Abstract is provided herewith on an Information Disclosure Statement. As described in the Abstract, two groups of sows were fed different diets during day 16-28 of gestation, one control group (normal arginine level of day 18 g/day; arginine/lysine ratio of 1.5) and one group which received a feed in accordance with the present invention (25g extra arginine resulting in an arginine level of $18 + 25 = 43$ g/dy; arginine/lysine ratio of 3.6). The experiment shows the surprising technical effect with respect to improved reproductive performance of a diet having an arginine/lysine ratio of more than 1.5.

Further, as Wilson et al. and Mahan fail to teach or suggest the specific amounts of arginine and other amino acids of the claims, they cannot disclose the presently claimed "structure" and cannot be capable of performing its intended use. *See e.g.*, December 11, 2006, Office Action, page 5.

Accordingly, a *prima facie* case of obviousness cannot be established because the cited references do not alone, or in combination, teach or suggest each and every element of any of claims 1-3 and 5-20. Moreover, the applicant respectfully submits that one of ordinary skill in the art would not have been motivated to combine the cited references and, in light of the NRC report, one of ordinary skill in the art would have been led away from combining the cited references.

Therefore, it is requested that the rejection of claims 1-3 and 5-20 under 35 U.S.C. § 103(a) be withdrawn.

CONCLUSION

In view of the foregoing amendments and remarks, the applicant submits that the claims define patentable subject matter and a notice of allowance is requested. Should questions exist after consideration of the foregoing, the Office is kindly requested to contact the applicant's attorney at the address or telephone number given herein.

Respectfully submitted,



Krista Weber Powell
Registration No. 47,867
Attorney for Applicant
TRASKBRITT
P.O. Box 2550
Salt Lake City, Utah 84110-2550
Telephone: 801-532-1922

Date: March 12, 2007
KWP/lmh
Document in ProLaw